K030471

Section B

510(k) Premarket Notification Summary for OPHTEC Enclavation Needles

APR 17 2003

Trade name: OPHTEC Enclavation Needle

Common name: Enclavation Needle

Classification name: 86HNQ, Ophthalmic Hook

Substantially Equivalent to: Stephens Disposable Hooks (K022842)

Description of Device: Enclavation Needles are surgical stainless steel needles that have been dulled and molded into a configuration so as to assist in tissue manipulation during ARTISAN™ Lens implant surgery. The instrument has an acrylic handle and one needle at each end. Each end is uniquely designed to create a right-hand end and a left-hand end to aid the surgeon during the procedure.

Submitted by: Rick McCarley
President & CEO
OPHTEC USA

Address: OPHTEC USA
6421 Congress Avenue, Suite 112
Boca Raton, FL 22487

Telephone: (561) 989-8767

Contact Person: Rick McCarley

Date Prepared: February 10, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 7 2003

OPHTEC USA
c/o Mr. Rick McCarley
6421 Congress Avenue, Suite 112
Boca Raton, FL 22487

Re: K030471
Trade/Device Name: OPHTEC Enclavation Needle
Regulation Number: 886.4350
Regulation Name: Ophthalmic Hook
Regulatory Class: I
Product Code: HNQ
Dated: February 10, 2003
Received: February 12, 2003

Dear Mr. McCarley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030471

Device Name: OPHTEC Enclavation Needle

Indications For Use:

An OPHTEC Enclavation Needle is a hand held, non powered, single-use ophthalmic instrument used to manipulate iris tissue during the surgical procedure to fixate an ARTISAN™ phakic or aphakic intraocular lens in a human eye.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030471

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)